DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Our Reference No.: 99-0678

October 1, 1999

Nancy L. Kercher
Immunex Corporation
51 University Street
Seattle, WA 98101-2936

Dear Ms. Kercher:

Your request to supplement your biologics license application for Etanercept to include revisions to the Warnings, Precautions, and Adverse Reactions sections of the package insert to address concerns associated with sepsis and serious infections has been approved.

Please submit three copies of the final printed labeling at the time of use and include part II of the label transmittal form with completed implementation information.

This information will be included in your biologics license application file.

Sincerely yours,

Karen D. Weiss

Karen D. Weiss, M.D.
Director
Division of Clinical Trial
Design and Analysis
Office of Therapeutics
Research and Review
Center for Biologics
Evaluation and Research